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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/792,291	03/02/2004	James H. Coombs	NAGACO.074A	3167

7590 01/25/2008
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EXAMINER

YU, MELANIE J

ART UNIT	PAPER NUMBER
1641	

MAIL DATE	DELIVERY MODE
01/25/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/792,291	Applicant(s) COOMBS ET AL.	
	Examiner Melanie Yu	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-54 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-8 and 14, are drawn to a method of detecting and quantifying a cell type, classified in class 435, subclass 7.1.
 - II. Claims 9-12 are drawn to a method of making an optical bio-disc, classified in class 436, subclass 518.
 - III. Claim 13 is drawn to a method of using an optical bio-disc comprising rotating the disc to remove unbound cells, classified in class 435, subclass 287.1.
 - IV. Claims 15-21 are drawn to an optical bio-disc, classified in class 422, subclass 50.
 - V. Claims 22-25 are drawn to a method of using the optical bio-disc, classified in class 435, subclass 287.9.
 - VI. Claims 26-38 are drawn to a method of identifying and quantifying various cell types, classified in class 435, subclass 288.7.
 - VII. Claims 39-50 are drawn to a method of detecting and quantifying target cells with signal antibodies and reporter agents, classified in class 435, subclass 283.1.
 - VIII. Claims 51-54 are drawn to a method of detecting and quantifying a target cell by mixing and reporter agent with a sample, classified in class 435, subclass 287.3.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions of a) each of groups I, III and V-VIII and b) group II are patentably distinct. Inventions are unrelated if it can be shown that they are not disclosed as capable

of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions the different inventions have different modes of operation, different functions and different effects. The inventions of groups I, III, V and VI-VIII are drawn to a method of using an optical bio-disc which requires the steps of applying a sample of target cells and operating the bio-disc, which is not required by the method of group II. The method of group II is drawn to a method of making an optical bio-disc, which requires the steps of fabricating the bio-disc by providing encoded information, which are not required by the method of groups I, III, V and VI-VIII.

3. Inventions of groups I, III and V-VIII are directed to related methods of using a bio-disc. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have a materially different mode of operation, do not overlap in scope and are not obvious variants. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants. The method of group I requires a capture antibody that has affinity for a common surface marker on target cells, which is not required by the methods of groups III, V or VI-VIII. The method of group III requires rotating the optical bio-disc at a predetermined speed and time to remove unbound cells from the target zone, which is not required of the methods of groups I, V or VI-VIII. The method of group V requires the step of detecting tagged first cell type and a tagged second cell type, which is not required of the methods of groups I, III or VI-VIII. The method of group VI requires a third reporter agent, a first second and third type of surface marker and detection of a first second and third reporter agent, which are not required of the methods of groups I, III, V, VII or VIII. The

method of group VII requires signaling antibodies and reporter agents which are not required of the method of groups I, III, V or VIII, and also requires detecting the number of tagged and untagged cells, which is not required by group VI. The method of group VIII requires mixing a reporter agent with a sample, which is not required of the method of groups I, III, V, VI or VII.

4. Inventions of a) each of groups I, III and V-VIII and b) group IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product of group IV can be used in any of the materially different processes of groups I, III and V-VIII.

5. Inventions of group II and group IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product of group IV can be made by a materially different process such as attaching the capture antibodies to the active layer before applying the active layer to the substrate.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

a) the inventions have acquired a separate status in the art in view of their different classification;

b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

d) the prior art applicable to one invention would not likely be applicable to another invention;

e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of an invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144.

If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art,

the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Yu whose telephone number is (571) 272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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